TEXAS
Health and Human Services

Texas Department of State Health Services

John Hellerstedt, M.D.
Commissioner

Bamlanivimab Allocations in Texas
December 22, 2020

Summary:
As you may have heard, Texas Department of State Health Services (DSHS) has been tasked with allocating the novel monoclonal antibody treatment, bamlanivimab, to healthcare facilities across the state. Because bamlanivimab is authorized for use in outpatients, DSHS would like to have a better understanding of outpatient settings that are willing to provide this novel therapeutic. A survey of healthcare facilities is provided at the end of this document where facilities may register to become a provider of this scarce resource.

Background and Technical Information:
In November, the United States Health and Human Services (HHS) announced its plan to ship bamlanivimab -- the Eli Lilly monoclonal antibody treatment issued emergency use authorization (EUA) by the FDA Monday, November 9 -- to states as provided by the federal government.

Thus far, Texas has been given six allotments of bamlanivimab, totaling over 20,000 doses/treatment courses. The federal government initially directed that the product be distributed only to hospitals or hospital-affiliated facilities. Therefore, Texas Department of State Health Services (DSHS) allocated the bamlanivimab to acute care hospitals across Texas, prioritizing communities with high COVID-19 disease burden. However, the federal government is now allowing this product to be distributed to other types of facilities. These facilities may include nursing facilities and infusion centers, among others. Any receiving facility would need to have a pharmacy license and understand the conditions for use of the product, including reporting requirements.

The EUA permits the use of bamlanivimab for treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Importantly, bamlanivimab is **not** authorized for use in patients:
- who are hospitalized due to COVID-19, OR
- who require oxygen therapy due to COVID-19, OR
- who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

A few additional facts:

- At this time, the product will be provided free of cost, and healthcare facilities will be able to charge an administration fee.
- It should be administered to the patient as soon as possible after a positive viral test for SARS-CoV-2 and within 10 days of symptom onset.
- Bamlanivimab needs to be administered via a one-hour infusion process; patients will need to be observed for another hour to ensure there is no hypersensitivity reaction.
- Bamlanivimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS) as necessary.
- Precautions should be put into place to ensure that infectious COVID-19 patients do not transmit the infection to other people in the facility.
- Administered doses must be reported via ImmTrac2 and the TDEM/DSHS Therapeutics Reporting portal.
- Additional technical information about administration of bamlanivimab can be found at DSHS COVID-19 Therapeutics.
- Bamlanivimab is distributed by AmerisourceBergen in accordance with the allocation plan supplied by DSHS. An account will need to be established with AmerisourceBergen prior to distribution of any product, and a representative from AmerisourceBergen will reach out to your facility point of contact prior to the delivery of any product.

Bamlanivimab is in limited supply, and some hospitals and healthcare facilities in Texas who request the treatment will not receive an allocation due to its scarcity. However, DSHS would like to ensure that there are providers across the state that are able to provide this therapeutic to higher risk individuals. If your facility has interest in becoming a provider of bamlanivimab, please respond to this survey. Some of the information for which you will be asked in the survey includes your facility's point of contact, address, phone number, email address, and pharmacy license number. Please read the bamlanivimab EUA and healthcare provider fact sheet prior to completing the survey to ensure that your facility and patient population will meet product use requirements.

DSHS appreciates everything that you and your facility is doing to keep Texans healthy and safe. Thank you for your consideration of becoming a provider of this novel therapeutic.